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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHIN, CHRISTOPHER L	

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1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,392	SMITH ET AL.	
	Examiner	Art Unit	
	Christopher L. Chin	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 27-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 is vague. The last line of the claim recites a phrase that is not clear - "which specifically being components of said sample". The recitation of "components" is also not clear since the claimed system is supposed to detect glycated albumin, not "components".

Claims 28 and 29 are vague because they do not further limit the system of claim 27. Claims 28 and 29 recite method steps which do not further limit a system.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 27-39 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al in view of Chudzik et al and Kang et al.

Yamamoto et al (EP 0 769 697 A1) discloses a method and dry test apparatus for simultaneously determining total albumin and glycated albumin. The test apparatus comprises (a) a support having thereon a developing layer; (b) blood cell separating layer; (c) a reagent layer containing albumin-staining dye (dye 1) and a glycated albumin staining dye (dye 2); (d) a measuring layer having fixed thereto an albumin-binding substance; and (e) a residual liquid absorbing layer. Parts (b)-(e) are arranged sequentially on the developing layer (col. 2, line 44, to col. 3, line 15). Figure 4A shows an embodiment of the apparatus where two separate test strips (2) and (2') are provided for measuring albumin and glycated albumin (col. 6, line 44, to col. 7, line 49). Albumin staining dye 1 can be a dye labeled anti-albumin antibody. Glycated albumin staining dye 2 can be a dye labeled anti-glycated albumin antibody. The anti-albumin and anti-glycated albumin antibodies can be either monoclonal or polyclonal antibodies (col. 9, lines 9-58). Figure 6 shows an embodiment where the apparatus includes a rigid housing that encloses 2 test strips. Albumin and glycated albumin with attached dye are detected on the test strips with equipment for photometry. A ratio of glycated albumin to albumin in a blood sample is calculated from the measurement (col. 5, lines 23-32).

Yamamoto et al differs from the instant invention in failing to teach 1.) a common sample application pad that directs sample fluid into the two separate test strips (2) and

(2') and, 2.) the use of particle labels instead of dyes to tag the anti-albumin and anti-glycated albumin antibodies.

Chudzik et al (US Patent 5,981,298) teaches the use of dyes or particles, such as colloidal metal particles or sol particle that are colored or colored polymeric particles, to label immunoreagents on test strips (col. 6, lines 51-65). As shown in the figures, a single common sample pad is shown that directs sample liquid into the separate test strips.

Kang et al (US Patent 5,559,041) teaches using metal sols, dye sols, or particulate latex as labels for tagging immunoreagents used on test strips (col. 8, lines 13-18). Figure 5 shows an embodiment where a single sample application pad (310) functions to receive a sample fluid and each of the test strips receive sample fluid from the sample application pad.

It would have been obvious to one of ordinary skill in the art to incorporate a single common sample application pad, as taught by Chudzik et al and Kang et al, to link the test strips of Yamamoto et al because the single common sample application pad provides the advantage of obviating the need to apply sample fluid to each of the test strips (2) and (2'). A single application of sample to common sample application pad allows sample fluid to migrate into each of test strips (2) and (2').

It would have been obvious to one of ordinary skill in the art to substitute particle labels, as taught by Chudzik et al or Kang et al, for the dyes used by Yamamoto et al to label the anti-albumin and anti-glycated albumin antibodies because (1) Chudzik et al shows that dyes and particle labels are functionally equivalent and interchangeable for

labeling immunoreagents; and (2) Chudzik et al and Kang et al show that particle labels are well known and conventionally used in test strips.

5. Claims 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al in view of Chudzik et al and Kang et al, as applied to claims 27-39 and 44, and further in view of Galen et al.

See above for the teachings of Yamamoto et al, Chudzik et al, and Kang et al.

Yamamoto et al, Chudzik et al, and Kang et al differ from the instant invention in failing to teach a reflectance spectrometer or fluorometer with the specific features recited in claims 40-43 to read their test strip.

Galen et al (US Patent 6,670,192 B1) discloses a method for measuring glycated albumin in a bodily fluid using a test strip and measuring instrument that measure albumin and glycated albumin. The measuring instrument comprises reflectance spectrometer with a first and second LEDs for measuring detection zones on the test strip, an internal computer chip for measurement and calculation, a liquid crystal display, an external port to transfer data, a battery power source, a rigid external case with an aperture for inserting a test strip, and memory for storing test results (cols. 13-14).

It would have been obvious to one of ordinary skill in the art to use the spectrometer of Galen et al to read the test strips of Yamamoto et al, as modified by Chudzik et al and Kang et al, because Yamamoto et al specifically teaches using a spectrometer to read their test strip and Galen et al specifically teaches using their

spectrometer to read test strips, like those of Yamamoto et al, that are for detecting albumin and glycated albumin.

Response to Arguments

6. Applicant's arguments with respect to claims 27-44 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher L. Chin/
Primary Examiner, Art Unit 1641

1/2/09